

Response from Carol Henry, American Chemistry Council in email of October 1, 2001

Response to Anderson request of 10-1-01 on the SAB Subcommittee on Policies and Procedures

Question 1: What information about panelists would be useful?

We believe that the existing conflict-of-interest rules are adequate, insofar as we are familiar with them, and they will evoke the kinds of information needed. The issue is how to follow the rules, rather than how to create new ones. Fundamentally, the activities of the panelists have to be weighed against the impacts of the outcome of the SAB report. Thus, the “missing” element is knowledge of the outcome of the report. In many cases, it will be obvious (e.g., the review of a risk assessment on a specific chemical). In other cases, it may be obscure (e.g., review of a research strategy). Unfortunately, there is a growing tendency to assign “guilt by association.” An expert who has some type of industry affiliation, whether it is a \$5K consultation a few years ago or current employment, should be judged by conflict-of-interest rules, not unfounded assumptions. One way to deal with this is to identify a threshold amount for disclosure. This would keep the focus where it should be—on items that might be influential.

Question 2: What do we need to know about the panel selection process?

The entirety of the process needs to be as transparent as is consistent with law. For example, the conflict-of-interest process (including blank forms) should be public (website). The review process used by the SAB to ensure the quality of the conflict-of-interest process should be public. The SAB should provide a public certification that it has followed its conflict-of-interest process on the specific review being addressed. This certification accommodates the requirements of privacy of certain information. The outcome of the report should be clarified (see above). The names and affiliations, along with a brief bio of the panelist should be public. The scientific disciplines covered in the material under review should be provided (e.g., to allow a comparison of the expertise needs with the expertise present as identified in the brief bios). The record of the meeting should reflect the verbal disclosures made by the panelists.

Question 3: What other areas should concern the Policies and Procedures Subcommittee?

The American Chemistry Council (Council) actively supports strong and effective policies and procedures to ensure the integrity of scientific advisory boards. Without such integrity, the credibility of a board's advice can be called into question. Expertise, independence, and balance are the three indispensable criteria for ensuring the credibility of review panels. None of these criteria must be neglected. While privacy rights of individuals must be respected (as defined by the U.S. Office of Government Ethics confidentiality rules), disclosure and transparency regarding potential conflicts-of-interest and bias are the critical mechanisms to ensure the expertise, independence, and balance of science advisory boards.

As the subcommittee seeks to address the concerns raised in the GAO report, they must ensure that the positive elements of the report and the ultimate goal of peer review not be damaged. Such a risk exists. The goal of the typical SAB peer review is that *experts* provide review and input to what other knowledgeable people have written. Experts often attain that status because they have conducted research in the topic area of the report. Also, they are well recognized in the field and therefore might have been invited to consult with others on similar topics. If SAB automatically deems such activities as a conflict or a bias, it would rule out most experts. The issue is one of degree. Most reports being reviewed by the SAB rest on a foundation of many publications, so authors of a small percentage of them would not be a problem. Contrast this to a report founded on a very few publications of which the SAB reviewer was the author of one of them. Also, there is a significant difference between a potential SAB reviewer who, as a consultant, has actively defended a finding/determination in court that is identical to the issue before the SAB and a reviewer who has participated in a workshop on the issue that is co-sponsored by a party with a point-of-view. The central nature of conflict-of-interest (i.e., will the reviewer or those close to him/her significantly benefit from the outcome of the review) always must be kept in mind. Taking \$5K as a consultant on a topic related to the review (from anyone) is different from receiving a substantial portion of one's income as a consultant on that same topic. The source of funds for a research project by the peer reviewer needs to be disclosed, but it is a minor issue, IF that research is published independently in the peer-reviewed literature.

The subcommittee's efforts should include a "cost-benefits" analysis of each recommendation made. In a situation like this, it is tempting to add more process layers, some of which are overkill or a substitute for simply following the rules in the first place. If each recommendation were analyzed for how well it improves the conflict-of-interest/balance/bias of panels (e.g., will it significantly improve things) and how many resources are needed (e.g., extra staff) allows for more rational decisions on follow-up actions.

Question 4: Are there other models or papers?

As the SAB is well aware, the NAS provides an excellent model and they are currently evaluating this issue further. It might be interesting to see a side-by-side comparison of other major federal models (e.g., FDA, NIH) and private models (e.g., major foundations that include peer review processes for funding decisions).

Question 5: Comments on Table of Responses to GAO

The SAB has done a thorough job of analyzing the GAO comments and developing solutions, most of which are achievable. It is especially useful to identify where assistance is needed to ensure the support you require. Our only concern relates to the B2 discussion. Details follow.

Quote from SAB Response to GAO "B2: Before appointing panel members, discuss other information relevant to assessing impartiality, such as research conducted and previous public statements or positions on the matter being reviewed, interest of the employer or clients in the matter, participation in legal proceedings, work for chemical companies or other affected industries and prior or current research grants that could be affected by the matter."

The problem: Response B2 only addresses a small part of the potential range of compromise or impartiality. It correctly calls for information such as previous research and positions taken. It is important to understand the interest of the employer or clients. It is also important to know about “work for chemical companies or other affected industries.” However, by singling out “chemical companies” or “industries,” it does not address work performed for other affected interest groups, such as academia, health effect testing contractors, environmental interest groups, and a countless list of others who could be affected by an SAB finding. The coverage needs to be broad because SAB deals with many issues, not just review of a specific chemical assessment that would affect a specific chemical company. For example, research needs reviewed by or produced by the SAB have an impact on funds available for certain types of research (e.g., academia and private research organizations). Also, having chemical companies and industries singled out suggests the appearance of bias, which is the very thing the SAB is trying to avoid.

The solution: The language in the quote “interest of the employer or clients” comes close to full coverage. If the language were broadened to say “interest of the employer, clients, or organization providing funding to the reviewer,” full coverage results, and the language “work for chemical companies or other affected industries” could be deleted. Examples are given below of how the new language will adequately detect issues for closer examination.

- Example 1. A reviewer works for a chemical company that produces a chemical under evaluation by SAB. The new language would identify this as potential conflict/bias for more in depth evaluation.
- Example 2. A reviewer works for the chemical industry that would be impacted by a change in health testing requirements. This new language would identify this as potential conflict/bias for more in depth evaluation.
- Example 3. A reviewer has been a consultant to a large Contractor that does chemical screening according to EPA guidelines, and the SAB committee is reviewing revised guidelines. This new language would identify this as potential conflict/bias for more in depth evaluation.
- Example 4. A reviewer is employed by an environmental group that has taken a strong, public position on the issue under SAB evaluation. This new language would identify this as potential conflict/bias for more in depth evaluation.
- Example 5. A reviewer is a university professor who may ultimately bid on the research that will flow from the SAB recommendations. This new language would identify this as potential conflict/bias for more in depth evaluation.